IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS WACO DIVISION

DEXCOM, INC.,

Plaintiff,

Civil Action No. 6:21-cv-00690-ADA

v.

ABBOTT DIABETES CARE, INC. ABBOTT DIABETES SALES CORP.,

Defendants.

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

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Rule 12(b)(6)

Plaintiff DexCom, Inc. ("DexCom") hereby opposes the motion to dismiss its induced infringement claims filed by Defendants Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp (collectively "Abbott"). (ECF 34.)

PRELIMINARY STATEMENT

Consideration of Abbott's motion to dismiss DexCom's induced patent infringement claims is premature in light of Abbott's parallel Rule 12 motion to dismiss for improper venue, and the motion invites a waste of judicial resources given that DexCom may amend any perceived deficiency in its induced infringement claims as a matter of course at such an early juncture in the case. On the merits, Abbott's motion misstates the applicable legal standard, demands facts not required of a complaint, and ignores the array of Abbott documents and statements – quoted at length – on which DexCom rests those claims.

First, as Defendants acknowledge, the Court should not rule on the merits of DexCom's claims until it has determined that venue is proper, a decision the Court will not render until 2022 under the schedule for venue discovery.

Second, Abbott's Rule 12(b)(6) challenge relies on the incorrect assertion that DexCom has not pleaded inducement with sufficient specificity. Texas courts have found substantively similar allegations sufficient to pass muster under the *Iqbal/Twombly* standard and have not adopted the heightened pleading requirement advocated by Abbott. Defendants ignore key aspects of DexCom's allegations and the principle that the Court is required to review a complaint "as a whole" when deciding a Rule 12(b)(6) motion. Such a holistic review confirms that the Amended Complaint is sufficiently specific.

Finally, even if the Court were to find a technical deficiency in DexCom's induced infringement allegations, leave to amend should be freely given because Defendants have not

shown—nor even attempted to argue—undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice, or futility in said amendment.

For these reasons, DexCom respectfully requests that Defendants' motion to dismiss for failure to state a claim be denied.

FACTUAL AND PROCEDURAL BACKGROUND1

DexCom is a pioneer in the field of continuous glucose monitoring systems ("CGMs"), critical products for the more than 34 million Americans living with diabetes. The asserted DexCom patents represent some of the innovations that enhance its industry-leading CGMs: U.S. Patent Nos. 11,000,213 ("'213 Patent"), 10,980,452 ("'452 Patent"), 10,702,215 ("'215 Patent"), 10,702,193 ("'193 Patent"), and 10,993,642 ("'642 Patent") (collectively the "Patents-in-Suit"). (ECF 19, Am. Compl. ("AC"), ¶ 2.)

Defendants have infringed and continue to infringe the Patents-in-Suit through, among other things, the sale of their glucose monitoring devices: the FreeStyle Libre products. (AC ¶ 34.) Accordingly, DexCom filed its original Complaint on June 30, 2021. (ECF 1.) DexCom amended the Complaint on July 12, 2021 to include a Certificate of Correction for the '642 Patent. (ECF 19.)

DexCom alleges that "Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least [one] independent" claim of each of the Patents-in-Suit. (*See*, e.g., AC ¶¶ 37, 46, 58, 71, 87.) DexCom further alleges that Abbott "has actively induced and continues to actively induce infringement by end-users of at least one claim" of each Patent-in-Suit. (*Id.* ¶¶ 42, 54, 67, 83, 92.) For each patent, DexCom alleges:

Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs,

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¹ All internal quotations marks and citations have been omitted, unless noted otherwise.

and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims.

(*Id.*) Thereafter, on a patent-by-patent basis, DexCom identifies exemplary evidence from sources such as user manuals (*e.g.*, *id.* at ¶¶ 40, 52, 73, 90) of the manner in which Abbott designed the products and instructs its customers to use them in an infringing way.

On September 20, 2021, Defendants moved to dismiss the Amended Complaint for improper venue under Rule 12(b)(3) and 28 U.S.C. § 1400(b) and, in the alternative, to dismiss DexCom's induced infringement allegations under Rule 12(b)(6). (ECF 34.) Defendants argue that DexCom's induced infringement claims rest on "generic allegations . . . insufficient to plead specific intent to induce infringement they do not identify any 'particular statement or material that plausibly suggests Defendants intend to induce infringement of the [Patents-in-Suit]." (*Id.* at 16.) As explained below, Defendants are incorrect, and their motion should be denied.

LEGAL STANDARD

A complaint survives a motion to dismiss if its facts, accepted as true, "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Facial plausibility requires that the plaintiff "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The court's inquiry should focus on the complaint as a whole, "regardless of how much of it is discussed in the motion to dismiss." *Wilson v. Birnberg*, 667 F.3d 591, 595 (5th Cir. 2012). "Dismissal is improper if the allegations support relief on *any possible theory*." *Id.* (quoting *Cinel v. Connick*, 15 F.3d 1338, 1341 (5th Cir. 1994)).

"For an allegation of induced infringement to survive a motion to dismiss, a complaint must plead facts plausibly showing that the accused infringer 'specifically intended [another] to Indus., Inc. v. Trim–Lok, Inc., 869 F.3d 1372, 1379 (Fed. Cir. 2017) (quoting In re Bill of Lading Transmission & Processing Sys. Patent Litig., 681 F.3d 1323, 1339 (Fed. Cir. 2012)). Thus, to survive a motion to dismiss under Rule 12(b)(6), plaintiffs bringing induced infringement claims must allege defendants: "(1) had actual knowledge of the patent; (2) knowingly induced a third-party to infringe the patent; and (3) had specific intent to induce the patent infringement. Affinity Labs of Texas, LLC v. Blackberry Ltd., 2014 WL 12551207, at *2 (W.D. Tex. Apr. 30, 2014) (citing DSU Med. Corp. v. JMS Co, Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006)).

However, a plaintiff need not "prove itself at the pleading stage." *Bill of Lading*, 681 F.3d at 1339. Though indirect infringement allegations must "comply with the . . . pleading requirements of *Iqbal* and *Twombly* under Federal Rule of Civil Procedure 8," no "heightened pleading standard is required." *KIPB LLC v. Samsung Elecs. Co.*, No. 219CV00056JRGRSP, 2020 WL 1500062, at *1–4 (E.D. Tex. Mar. 9, 2020), *report and recommendation adopted*, No. 2:19-CV-56-JRG-RSP, 2020 WL 1495725 (E.D. Tex. Mar. 27, 2020).

<u>ARGUMENT</u>

I. THE COURT SHOULD DECIDE WHETHER VENUE IS PROPER BEFORE REACHING THE MERITS OF DEFENDANTS' MOTION TO DISMISS

Given Defendants' pending motion to dismiss for improper venue and the discovery underway relating to the issues presented by that motion (ECF 35), the Court should defer consideration of Defendants' motion to dismiss for failure to state a claim. *Tesoro Ref. & Mktg. Co. LLC v. C.A.R. Enterprises, Inc.*, 2018 WL 6050603, at *12 (W.D. Tex. Nov. 19, 2018) ("The Court must reserve ruling on the 12(b)(6) motion until it determines the issues of subject matter jurisdiction and venue.") Defendants acknowledge this. (ECF 34 at 15.)

II. THE AMENDED COMPLAINT PROPERLY STATES CLAIMS FOR INDUCED INFRINGEMENT AS TO ALL PATENTS-IN-SUIT

Defendant's Motion does not challenge the sufficiency of DexCom's pleading of knowledge or infringement. Instead, it raises only two alleged deficiencies: that the pleading fails to identify specific "statements in the alleged documentation [cited in the Amended Complaint] that allegedly encouraged a third party to infringe" and that the operative facts are not "pled on a defendant-by-defendant basis." (ECF 34 at 17-18.) However, neither is required by the law governing pleading under Rule 8, and, in any event, DexCom has provided extensive allegations, including by identifying specific user-facing documentation and excerpts therefrom, that satisfy *Iqbal/Twombly*. Defendants' challenge to the sufficiency of the induced infringement allegations should thus be denied.

A. The Amended Complaint Pleads the Elements of Induced Infringement.

Defendants do not dispute that DexCom adequately pleaded knowledge of the patent and infringement by Abbott and third parties (*i.e.*, Abbott's customers that use the accused Freestyle Libre products).² Nor could they: DexCom filed the original Complaint on June 30, 2021 and the Amended Complaint on July 12, 2021. (ECF 1, 19.) "[A] defendant's knowledge of a patent can be established through the filing of the complaint" where the complaint identifies the patents in question. *Affinity Labs of Texas, LLC v. Toyota Motor N. Am.*, 2014 WL 2892285, at *5 (W.D. Tex. May 12, 2014). Hence, "[o]nce the lawsuit is filed, *there is no question that a defendant has actual notice* of . . . patent infringement" necessary to sustain a claim for induced infringement." *Id.* (citing *Bill of Lading*, 361 F.3d at 1345-46). Nor do Defendants claim

² At a minimum, Defendants became aware of the Patents-in-Suit at the time the Complaint was filed and therefore had knowledge of DexCom's infringement allegations prior to the filing of the operative pleading, the First Amended Complaint. (Dkt. 19 at ¶¶ 38, 47, 59, 72.)

ignorance as to "the specific products alleged to infringe [or] the functionality of the products that infringe" – two details that push allegations of infringement from possible to plausible. *Script Sec. Sols. L.L.C. v. Amazon.com, Inc.*, 170 F. Supp. 3d 928, 937 (E.D. Tex. 2016). DexCom has identified the infringing FreeStyle Libre product lines (AC ¶ 34), and explained that they infringe DexCom's patented inventions relating to sensor calibration, sensor and sealing assembly design, and alerts/alarms for notifying users of critical glucose conditions. (*See, e.g., id.* at ¶¶ 30-34, 37, 48, 58, 73, 90.)

The crux of Defendants' motion is thus that DexCom allegedly fails to "specific[ally] identif[y]... any statement... that allegedly encouraged a third party to infringe." (ECF 34 at 17.) This is both incorrect as a factual matter and not the applicable standard. The Amended Complaint includes numerous quoted excerpts from Abbott instruction manuals instructing users to engage in use of the accused glucose monitoring devices in a manner that infringes the Patents-in-Suit.

The '213 and '642 Patents are directed to approaches to calibrating the accused sensor products. The Amended Complaint specifically alleges that Abbott induces users to infringe the '213 and '642 Patents by its "introduc[tion] into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices." (Id. ¶ 42.)

As set forth in Abbott's own literature quoted in the Amended Complaint: "The sensor sensitivity is determined during the sensor manufacturing process and that information is included with every sensor in the form of a sensor code. That code can be preprogrammed into the sensor electronics such that no user interaction is required to enter the code, eliminating the risk of transcription error." (*Id.* at ¶ 91.) Thus, it is the "very operation of [Abbott's] accused products"

that "constitutes a direct infringement" of claim 1 of the '642 Patent. Castlemorton Wireless, LLC v. Bose Corp., No. 6:20-CV-00029-ADA, 2020 WL 6578418, at *5 (W.D. Tex. July 22, 2020); see AC ¶ 41 (similar for the '213 Patent). And "any effort . . . to help its customers utilize" the accused components of the Libre 2 system (i.e., the sensor and sensor assembly), "necessarily results in customers' infringing" the patents. (Id.) Here, DexCom specifically identifies Abbott instructions that direct customers to use the infringing portion of the accused Libre 2 system – e.g., AC ¶ 40:

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor Measures your glucose while on your body (only visible after applied).

Libre 2 User Manual at 18.

Id. Abbott's directions induce infringement.

Similarly, the '452 and '193 Patents are directed to physical attributes of the sensor and sensor assembly – specifically, mechanical features of the sensor's sealing and electrical contact(s) (e.g., AC ¶¶ 52-53) and the "arrangement of layers for the transcutaneous sensor," (id. ¶¶ 33, 74-82). The "introduc[tion] into the stream of commerce of the Abbott Libre 2 systems and other infringing [Abbott products]" with instructions for use of the sensor by the user constitutes inducement. (Id. at ¶¶ 83, 92.) For each patent, DexCom identifies categories of user-facing documentation as well as at least one example of such documentation disseminated by Abbott that instructs users on use of the accused component of its glucose monitoring system. (Id. at ¶¶ 73,

90.) With respect to the '193 Patent, for example, the Amended Complaint cites the Libre 2 User Manual provision: "By following the instructions, you prepare and apply the Sensor [the accused component, with the infringing mechanical features] on the back of your upper arm." (*Id.* at ¶ 73.) For the '452 Patent, the Amended Complaint excerpts portions of the Abbott User Manual that provides details on use of the sensor assembly in water. (*Id.* at ¶ 52.)

Finally, the '215 Patent discloses a system that provides an output (e.g., a message to trigger an alarm) based its processors assessment of whether sensed glucose values meet user and non-user settable criterial. (AC ¶¶ 60, 63, 64.) DexCom alleges that the Alerts and Alarms feature(s) of the Abbott Libre 2 system infringe the '215 Patents and that Abbott induces its users' infringement by setting low and high glycemic alarms by default and instructing its users to set thresholds for such alarms. (AC ¶¶ 64-66 (citing Abbott Libre 2 User's Manual at 56-66).) The Amended Complaint cites exemplary portions of the Libre 2 User Manual that describe the functionality of Abbott's user-settable and non-user-settable alerts and alarms, the use of which constitutes direct infringement. (Id.)

Collectively, the Amended Complaint allegations sufficiently establish the specific intent element of induced infringement for each Patent-in-Suit. *See Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1204 (Fed. Cir. 2017) ("instruction manuals" teaching an infringing use supported both intent to induce and actual inducement). As this Court held in *Castlemorton Wireless, LLC v. Bose Corporation*, "any effort by [a defendant] to help its customers utilize the features of its accused products—including distributing how-to guides and other reference materials . . . [is] properly characterized as 'instruct[ions on] how to engage in an infringing use." 2020 WL 6578418, at *5 (W.D. Tex. July 22, 2020) (quoting *Metro–Goldwyn–Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)). Here, Abbott's marketing and user documentation,

including the specific examples cited in the Amended Complaint, evidence Abbott's specific intent to induce infringement. (*Id.* ¶¶ 37, 46, 58, 71, 87). "Common sense indicates that advertising that your product can be used in conjunction with [an infringing system] . . . gives rise to a reasonable inference that you intend to induce your customers to accomplish these benefits through utilization of the patented method." *Bill of Lading*, 681 F.3d at 1341–42; *see also MONKEYmedia, Inc. v. Twentieth Century Fox Home Ent., LLC*, 226 F. Supp. 3d 693, 707 (W.D. Tex. 2016) ("[I]nducement may be shown by 'advertising an infringing use or instructing how to engage in an infringing use'.") (quoting *Grokster*, 545 U.S. at 936).

Even if the Amended Complaint did not include these specific references, links, and screenshots to Abbott's statements inducing end users to infringe the Patents-in-Suit, it should nevertheless survive the motion to dismiss. A party pleading induced infringement "need not identify what the manuals specifically say, how the communications specifically instructed customers, which customers were specifically instructed, or which advertisements [were] published." *Motiva Pats., LLC v. Sony Corp.*, 408 F. Supp. 3d 819, 832 (E.D. Tex. 2019). Like the plaintiff in *Motiva*, DexCom identified classes of discoverable information likely to support it claims, including "manuals and technical literature describing and instructing in the operation of the accused devices in an infringing manner." (*E.g.*, AC ¶¶ 42, 54, 67, 83, 92.)

B. The Amended Complaint Does Not Engage in "Group Pleading."

Defendants also seek dismissal of DexCom's induced infringement claims under the group pleading doctrine, which may render a complaint insufficient for failing to distinguish between the conduct of multiple defendants. *See, e.g., United States v. Lakeway Reg'l Med. Ctr., LLC*, 2020 WL 6146571, at *2 (W.D. Tex. Feb. 13, 2020) (noting that the "explicit[] prohibit[ion]" on group pleading only applies to complaints alleging fraud reviewed under Rule 9(b)). For this proposition, they cite no binding precedent from this Circuit. Indeed, the one Texas federal court to consider

this argument in the context of induced infringement rejected it, acknowledging that "Courts have held that complaints that used collective terms to refer to acts of all defendants were sufficient under Rule 12(b)(6)." *Marking Object Virtualization Intel., LLC v. Hitachi Ltd.*, 2017 WL 11631001, at *3 (E.D. Tex. Sept. 25, 2017). Here, DexCom uses the collective term "Abbott" to refer to ascribed specific statements to two subsidiaries in the same corporate family. That is enough to diffuse any claims of group pleading in the Fifth Circuit, where the court has ruled that allegations relying on "sufficiently particularized" statements from Defendants – even if they are ascribed to all Defendants as a group – "do not constitute group pleading." *Owens v. Jastrow*, 789 F.3d 529, 538 n.4 (5th Cir. 2015).

III. IF THE COURT DOES NOT DENY THE MOTION, LEAVE TO AMEND SHOULD BE FREELY GIVEN

Should the Court nevertheless dismiss DexCom's induced infringement claims, the appropriate remedy would be leave for DexCom to amend. Defendants offer no argument to the contrary. Absent "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of a proposed amendment, . . . 'the discretion of the district court is not broad enough to permit denial'." *Plastic Specialties, Inc. v. JPMorgan Chase Bank, N.A.*, 476 F. Supp. 3d 523, 531 (W.D. Tex. 2020) (allowing second amended complaint) (quoting *Mayeaux v. La. Health Serv. & Indem. Co.*, 376 F.3d 420, 425 (5th Cir. 2004).) And where, as here, a party has once amended its complaint "shortly after [defendant] was served and before [Defendant] filed an answer," a party's second amendment should not be found to have caused unduly delay or to be in bad faith. *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 271 (5th Cir. 2010) (requiring "special circumstances [to] justify dismissal without leave to amend").

CONCLUSION

DexCom respectfully requests that the Court deny Defendants' Motion to Dismiss DexCom's induced infringement claims. In the alternative, DexCom respectfully requests that the Court grant DexCom leave to amend its First Amended Complaint.

DATED: October 4, 2021 Respectfully submitted,

By /s/ Charles Ainsworth

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service, are being served this 4th day of October, 2021, with a copy of this document via the Court's CM/ECF system.

/s/ Charles Ainsworth
Charles Ainsworth